REMARKS

Reconsideration of the above-identified application is respectfully requested.

The Abstract has been objected to for inclusion of the word "butyl" in a Markush grouping of polymers, since "butyl" is not a polymer. Applicant cannot locate the word "butyl" in the Abstract as filed, and therefore cannot take corrective action.

Claims 1-9 and 15-19 remain in the application. Claims 10-14 have been withdrawn.

Section 112 Rejections

Claims 2, 3, 15 and 17 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which was not disclosed in the specification. For example, the Examiner states that claim 2 recites the limitation "up to 30 days" and claim 15 recites the limitation "up to 14 days." The Examiner believes nowhere in the specification applicants disclose periods less than 14 days. However, at page 15, lines 10-14, it is stated "The amount of the antioxidant or other agent used is an amount sufficient to partly or completely fill the open foam cells 62 so that the antioxidant would be released in a time period ranging from 0 to about 14 to about 30 days onto or into the skin." Indeed, time periods less than 14 days are disclosed. From the quote, "0" means immediate release. Therefore, the release time could be from 0 or immediate release up to about 30 days, or up to about 14 days. Therefore, the lower limit can be open-ended.

Moreover, the lower limit is described again at page 11, lines 11-14 wherein it is stated, "Indeed, the open cells of the polymer foam of the present invention should be of a sufficient size to hold an amount of therapeutic active agent so that it can be released onto the skin through the polymer enrobing material for as much *as about 14 to about 30 days."* (emphasis added)

The lower limit is open since it is stated the polymer can be released for as much as about 14 days...which indicates an amount higher than expected. The expectation being that release times are less than 14 days.

Regarding claims 13 and 17, they have been deleted. Claim 18 remains, which describes an open-face pore having a diameter of about 200 to about 300 microns.

Claims 1-9 and 15-19 have been rejected under 35 U.S.C.§112, first paragraph, as failing to comply with the written description requirement for the Examiner believes that the specification lacks a description of therapeutic agents with regard to doses and concentration in combination with different polymers. On page 15, there is a description, which encompasses the quote cited on the previous page, of an antioxidant or other agent used in an amount sufficient to fill the voids of the foam so that it can be released in a period ranging from 0 to 14 days. This is shown at page 15, lines 10-20 to page 16, line 2, as follows:

> "The amount of the antioxidant or other agent used is an amount sufficient to partly or completely fill the open foam cells 62 so that the antioxidant would be released in a time period ranging from 0 to about 14 to about 30 days onto or into the skin. The amount cannot exceed the concentration that will go into and remain in the solution with silicone, if silicone is used as a polymer and enrobing material. If other materials are utilized as the polymer and enrobing material, they will determine the amount of therapeutic agent or additive. The amount of antioxidant that may be used in the present invention, when silicone is used as the enrobing material, may typically range from about 1 to about 10 percent by weight of the sheet, with about 1.5 percent to about 5 percent being preferred. The composite sheet of the present invention allows for the application of medication to the skin or scar tissue for long periods of time without the need for changing dressings."

One skilled in the art, upon selecting the enrobing material and the therapeutic agent, would know from reading the above description about how much therapeutic agent to add to the composite sheet of the present invention. Typically, the microchannels are filled with the therapeutic agent. The amount used to fill the microchannels may be the amount sufficient for one treatment. The therapeutic agent fills the microchannel and is released onto the skin and, secondly, disperses into the polyurethane gel where it is subsequently released to the skin.

Claims 4 and 5 have been rejected under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the invention for using the expressing "may be" in the claims. This expression has been deleted and the claims have been correctly amended.

Section 103 Rejections

Claims 1-9 and 15-19 have been rejected under 35 U.S.C.§103(a) as being unpatentable over U.S. Patent No. 5,352,508 ("the '508 patent") combined with U.S. Patent No. 6,326,410 ("the '410 patent").

The Examiner believes that the '508 reference teaches wound dressing comprising a net substrate encapsulated in a hydrophilic tacky resin coating leaving the apertures in the net substrate unoccluded. In other words, the coating contains holes. The coating is polyurethane that may contain active agents such as silver sulphadiazine. The Examiner states that the reference shows the coated substrate is laminated between two release liners. The Examiner admits that the reference does not teach the encapsulated layer to be a porous foam layer and does not teach the period of release of the therapeutic active agent and the core size.

The Examiner interprets the '410 reference as teaching polyurethane foam that is suitable for wound contact because it has low adhesion and can deliver active agents such as antimicrobial agents to the wound. The Examiner therefore believes it would be obvious to one skilled in the art to add the wound dressing comprising porous net substrate encapsulated with polyurethane with the teachings of the '410 reference to replace the net substrate with foam containing antibacterial agents. However, applicants believe this reasoning is incorrect. One skilled in the art would not read the '508 reference disclosing a net substrate with a tacky resin, thinking that it could become a porous substrate containing therapeutic agents for release onto the surface of skin. The apertures in the net, about 1 to about 3 millimeters, are nowhere close to the size needed to function as the pores in the present invention function to release and deliver therapeutic agents to the skin. Indeed, pore size matters. One skilled in the art would not look to a net substrate for holding and subsequently releasing medications because in effect there would be not holding function with a net having apertures of 1 to 3 millimeters.

Adding the teachings of the '410 reference to the '508 reference would not suggest the presently claimed invention.

The '410 reference contains high density polyurethane including .03 to 0.3 parts by weight of a natural synthetic rubber to increase cure time for the shrinkage of the gel on drying. The cells are about 0.1 to 0.6 millimeters in diameter. The cells of the foam, if intended to hold a therapeutic agent, are nowhere equivalent to the porous foam material having a diameter of 200-300 microns, nor are they equivalent to the applicants' microchannels as claimed in the present invention. In the present invention, the microchannels hold the therapeutic agent for release into the foam structure. The therapeutic agent used in the present invention can contact the skin through the micro-channels or through the pores of the foam structure. Knowing the size of the cells of the structure of the '410 reference, one skilled in the art would not utilize that structure, alone or in combination with the teachings of the net substrate of the '508 reference.

Neither the '508 nor the '410 references disclose micro-channels for holding and dispensing a therapeutic agent. The therapeutic agent is dispensed directly onto the surface of the skin. The micro-channels also served to disperse the therapeutic agent throughout the polyurethane gel for additional dispensing of the therapeutic agent to wide areas of the skin or wound being treated. The therapeutic agent is held and dispensed from pores in the polyurethane allowing for a timely and wide-spread distribution of the agent for effective treatment on the skin or wound surface. The microchannels are clearly seen in Figs. 1-4 of the present application. The references taken alone or in combination do not teach, suggest or motivate one skilled in the art to prepare the composite sheet claimed in the present invention.

Claims 1-9 and 15-19 have been rejected under 35 U.S.C. § 103 as being unpatentable over DE 2946553 (the '553 patent) in view of the '410 patent.

The examiner states it would have been obvious to prepare a wound treating device comprising a gelatinous polymer covered with a porous material, for example, polyurethane foam, as allegedly disclosed in the '553 reference and replace the gelatinous polymer with the foam containing antibacterial agents as disclosed by the '410 reference. The examiner believes one skilled in the art would know the combination of teachings of the'553 and '410 references would produce a porous foam material for delivering therapeutic agents to the skin.

There are many conventional devices for delivering therapeutic agents to the skin, as shown by the examiner. Indeed, the Office Action recites the following in the first line of page 8, "The period of delivery of the therapeutic agent can be manipulated by the skilled artisan according to polymer, active agent and the condition to be treated." This statement doesn't consider the claimed invention. The structure of the composite sheet claimed herein provides for an improvement in the art. Therapeutic agents can be dispensed relatively quickly and up to about 14 to about 30 days in the same device. There is no teaching in the art cited that shows the structure and results of the presently claimed invention.

The '553 reference discloses a gelatinous polymer covered with a water-vapor and gas-impermeable membrane which may be cellulose fiber, polyamide or polycarbonate. In addition, the gelatinous polymer can be covered by a foliated woven fabric or non-woven fleece. Pore sizes in the membrane may range from 3 x 10^{-4} to 10 μm. The '553 reference does not teach a foam-like gelatinous material; it does not teach the retention of therapeutic agents, but relies on a storage tank for such purpose and does not teach the time period for releasing the therapeutic agent. Most importantly, it does not teach the use of micro-channels for retaining and delivering the therapeutic agent. The combination of the teachings of the '410 reference adds nothing to the teachings of the'553 reference. The combination of the references does not teach or suggest the use of micro-channels for retaining and delivering a therapeutic agent to the surface of the skin or wound as claimed in the present invention. Clearly, one skilled in the art would not be led to the claimed invention by the references, taken singly or in combination.

CONCLUSION

None of the references show a composite sheet for delivering therapeutic agents to the surface of the skin, wound or scar as claimed in the instant invention. Micro-channels cannot not be confused or equated with the pores of polyurethane foam. They are structurally diverse .The composite sheet of the claimed invention delivers therapeutic agents to the required area in relatively short or extended periods of time by the use of the micro-channels, in a porous polymer and enrobing material. Nothing in the cited art discloses these features.

It is submitted that the claimed invention meets the requirements of 35 U.S.C and therefore an early Notice of Allowance is respectfully requested.

Respectfully submitted,

By: 

W. Dennis Drehkoff
Attorney for Applicant
Registration No. 27,193

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RYNDAK & SURI LLP
200 West Madison Street
Suite 2100
Chicago, IL 60606
(312) 214-7770